

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Human and Animal Food Operations

Effective Date: December 14, 2018

1. Office of Human and Animal Food Operations (DCIE).

- A. Oversees program directors in the coordination, interpretation and evaluation of the Food and Drug Administration's (FDA) overall field inspections and compliance efforts in the areas of human and animal food and other products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM).
- B. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other senior FDA leaders on human and animal food inspection, compliance and other field activities.
- C. Coordinates human and animal food operations with the Office of Enforcement and Import Operations and the Office of Regulatory Science; supports human and animal food partnerships and policy through collaboration with the Office of Partnerships and Policy.
- D. Evaluates the overall management and capabilities of the FDA's human and animal food field organization; initiates action to improve the management of global human and animal food field activities.
- E. Oversees and coordinates human and animal food related recalls, consumer complaints, and quality system activities.
- F. Develops, issues, and approves proposals and instructions affecting global human and animal food field operations.
- G. Develops, clears, issues and maintains guidance to the field in the Investigations Operations Manual relative to human and animal food.

- H. Promotes the need for prompt and positive action within the FDA to assure safe human and animal food products.
- I. Directs and coordinates the Office of Regulatory Affairs (ORA) emergency preparedness and response activities relative to human and animal food.
- J. Participates, where appropriate, in international cooperation activities relative to human and animal food.

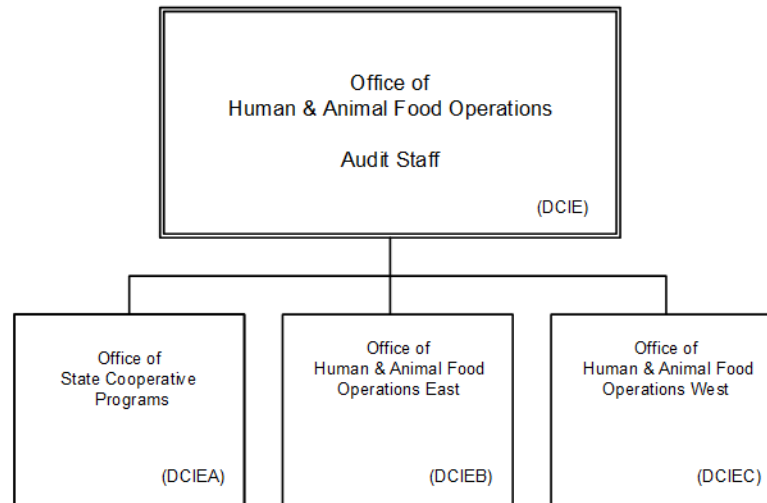
2. Audit Staff (DCIE)

- A. Conducts audits of domestic and international regulatory partners to measure their performance against program standards. Audits include reviews of regulatory systems and more specifically the inspection, investigation, sample collection and analysis, enforcement, response, recovery, and/or outreach components of these regulatory systems.
- B. Coordinates with other ORA units on the development of training and certification programs for regulatory partners.
- C. Supports the development of program standards and associated audit programs that may apply to international and/or State regulatory partners and ORA.
- D. Represents ORA and coordinates ORA participation on FDA workgroups responsible for comparability assessments and equivalence determinations of foreign regulatory partners.

3. Authority and Effective Date.

The functional statements for the Office of Human and Animal Food Operations were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Human and Animal Food Operations**



Division of Retail Food Protection
Division of Milk Safety
Division of Shellfish Sanitation

Division of Foreign Human &
Animal Food Operations East
Division of Human & Animal Food
Operations East I
Division of Human & Animal Food
Operations East II
Division of Human & Animal Food
Operations East III
Division of Human & Animal Food
Operations East IV
Division of Human & Animal Food
Operations East V
Division of Human & Animal Food
Operations East VI

Division of Domestic Human &
Animal Food Operations
Division of Human & Animal Food
Operations West I
Division of Human & Animal Food
Operations West II
Division of Human & Animal Food
Operations West III
Division of Human & Animal Food
Operations West IV
Division of Human & Animal Food
Operations West 5
Division of Human & Animal Food
Operations West VI

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Human & Animal Food Operations organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Human & Animal Food Operations (DCIE):

Audit Staff

Office of State Cooperative Programs (DCIEA)

Office of Human & Animal Food Operations East (DCIEB)

Office of Human & Animal Food Operations West (DCIEC)

These organizations report to the Office of State Cooperative Programs (DCIEA):

Division of Retail Food Protection

Division of Milk Safety

Division of Shellfish Sanitation

These organizations report to the Office of Human & Animal Food Operations East (DCIEB):

Division of Foreign Human & Animal Food Operations East

Division of Foreign Human & Animal Food Operations East I

Division of Foreign Human & Animal Food Operations East II

Division of Foreign Human & Animal Food Operations East III

Division of Foreign Human & Animal Food Operations East IV

Division of Foreign Human & Animal Food Operations East V

Division of Foreign Human & Animal Food Operations East VI

These organizations report to the Office of Human & Animal Food Operations West (DCIEB):

Division of Foreign Human & Animal Food Operations West

Division of Foreign Human & Animal Food Operations West I

Division of Foreign Human & Animal Food Operations West II

Division of Foreign Human & Animal Food Operations West III

Division of Foreign Human & Animal Food Operations West IV

Division of Foreign Human & Animal Food Operations West 5

Division of Foreign Human & Animal Food Operations West VI